

Exhibit A

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

v.

This Document Relates To:

MARY A. LAMBERT,
Plaintiff,

v.

LIBERTY INDUSTRIES, INC.,
UNIFIRST CORPORATION, A/D/B/A
UNICLEAN CLEANROOM SERVICES,
Defendants.

MDL No. 2419

Master Docket: 1:13-md-2419-RWZ

Civil Action No. 1:13-cv-10351-RWZ

AFFIDAVIT OF JEFFREY ERICKSON

I, Jeffrey Erickson, upon oath, do depose and say as follows:

1. I am currently employed as Engineering Manager of Liberty Industries, Inc. (“Liberty”) and have held that position since January, 2014. I have been employed fulltime by Liberty in various capacities starting in September, 1997 through March, 2000 and again starting in August, 2005 through to the present. I was the person responsible for the architectural construction by Liberty and its subcontractors of three cleanrooms at the New England Compounding Center (“NECC”) on Waverly Street in Framingham, Massachusetts (“the Facility”) in 2005, 2006 and 2008 (collectively “the Cleanrooms”). The 2005 and 2006 Cleanrooms were constructed for NECC and the 2008 Cleanroom was constructed for Ameridose. I was present at the Facility on a regular basis during construction of the Cleanrooms. I also am knowledgeable concerning the Cleanrooms based upon my personal

familiarity with the contract documents, personal observations made during construction and an inspection of the premises on July 9, 2014. In addition, I am familiar with Liberty's recordkeeping with respect to its contracts with NECC, the documentation relating to the performance of the work, the testing that was done in connection with the closeout of the projects, and the acceptance of the Cleanrooms by NECC.

2. Attached hereto as **Exhibit 1** is a copy of correspondence sent to NECC on November 21, 2005, outlining Liberty's proposal for construction of the 2006 Cleanroom. Attached hereto as **Exhibit 2** is a copy of NECC's acceptance of Liberty's proposal, dated November 28, 2005. Overall, the work that Liberty performed in the construction of the Cleanrooms included construction of the walls and ceilings of each Cleanroom, but did not include:

- a. The preparation of the floors;
- b. The design and installation of the HVAC systems that supplied air to and vented air from the Cleanrooms;
- c. All work benches, the hoods or any other furnishings or equipment contained within the Cleanrooms;
- d. The electrical system; or
- e. The fire suppression system.

3. All of the equipment (hoods, benches, shelves) and furnishings in the Cleanrooms were specified, supplied and installed by NECC.

4. The HVAC system and all related piping and duct work was designed and installed by Victory Mechanical pursuant to agreements it had directly with NECC.

5. Liberty provided operations and maintenance manuals to NECC which contained general information regarding cleanroom operation and suggested practices for cleaning, maintenance of cleanrooms and formal third party certification report. In addition, Liberty offered training in the proper operation of the Cleanrooms, without charge, to NECC (as Liberty does for all of its customers), but NECC did not accept the offer for training.

6. NECC defined the class of the cleanrooms it wished constructed and Liberty built them pursuant to specifications required by NECC. Each of the cleanrooms constructed by Liberty actually contained at least three rooms. There was a small personnel gowning room and preparation and/or product room, attached to a larger main room in which work customarily was performed.

7. Under Liberty's contracts with NECC for the 2005 and 2006 Cleanrooms, and under its contract with Ameridose for the 2008 Cleanroom, the ambient air in the Cleanrooms was required to meet the standard incorporated into the contract. That standard was ISO Standard 14664-1. "ISO Standard 14644-1" refers to a standard developed by the International Organization for Standardization ("ISO"), a worldwide federation of national standards bodies, that applies to cleanrooms and related controlled environments. ISO 14644 is comprised of several parts that pertain to particular aspects of cleanrooms. ISO 14644-1 provides the standard for classifying air cleanliness in cleanrooms. Under that standard, cleanrooms are required to meet certain parameters for pressure, and no more than a maximum number of particles greater than 0.5 microns in size per cubic meter or cubic foot. The number of particles per cubic meter or cubic foot depended upon the particular class of the cleanroom. The number of particles for Classes 4 through 8 are identified below:

Class	Particles Per m ³	Particles Per ft ³
4	352	10
5	3,520	100
6	35,200	1,000
7	352,000	10,000
8	3,520,000	100,000

Typically, the main room of the Cleanrooms is the lowest class, and by definition cleaner than the smaller personnel, preparation or freight rooms adjacent to it. For example, the largest of the cleanrooms constructed in 2006 consisted of a Class 8 Freight Anteroom, a Class 7 Personnel Anteroom,¹ a Class 7 Preparation Room and a Class 6 Main Room. The Cleanrooms were to function under positive pressure such that the air would flow from the lowest class room out to the higher class room. In the 2006 Cleanroom, the positive pressures are higher in the lower numbered class room. Thus, if a door were opened, air would flow from the Class 6 room to the Class 7 rooms and then to the Class 8 room.

8. The air flow within the Cleanrooms was designed to flow from the cleanest area to the dirtiest area based on room pressures when the HVAC system was operating. The return grilles in a cleanroom were designed to move the air in uninterrupted, parallel routes, *i.e.*, laminar flow. Blocking the return grilles impedes the proper flow of air, causing excessive turbulence which can stir up particles. Turning off the HVAC system also prevents a cleanroom from maintaining a controlled environment with consistent temperature and pressure.

9. The 2005 Cleanroom contained a Class 8 Anteroom and a Class 7 Main Room (collectively, the “2005 Cleanroom”). The 2008 Cleanroom contained a Class 7 Freight Anteroom, a Class 7 Personnel Anteroom, a Class 6 Preparation Room and a Class 5 Main Room (collectively, the “2008 Cleanroom”).

¹ The Personnel Anteroom for the 2006 Cleanroom was specified as a Class 7 anteroom. *See* Exhibit 1. However, when it was certified by the third-party testing company, it functioned at the level of a Class 6 room and was therefore certified as a Class 6 room.

10. The 2006 Cleanroom was completed and accepted by NECC in August 2006. *See* Aug. 11, 2006 Job Completion Sign-Off Sheet and related correspondence, true and correct copies of which are attached hereto as **Exhibit 3**. There were a few punch list items that remained to be resolved once the job was concluded, but NECC agreed to relieve Liberty of any need to take action on them. *See id.* At no time did Liberty ever refuse to perform work for NECC, or ignore any requests for repair or other work.

11. The 2006 Cleanroom was certified as compliant with ISO 14644-1 on July 12, 2006. *See* Jul. 12, 2006 Cleanroom Certification Report, a true and correct copy of which is attached as **Exhibit 4**.² The 2005 and 2008 Cleanrooms were also certified in compliance with ISO 14644-1 after construction. *See* Oct. 7, 2005 Cleanroom Certification Report, a true and correct copy of which is attached as **Exhibit 6**, and Mar. 6, 2008 Cleanroom Certification Report, a true and correct copy of which is attached as **Exhibit 7**.

12. Each cleanroom, specifically each component room within the cleanroom, was tested and met the regulatory standard for that component room. For example, the Class 6 main room of the 2006 Cleanroom was required to have fewer than 1,000 particulates per cubic foot. The average measured at the time of testing was 55.44 particulates per cubic foot. *See* Exhibit 4. A summary of the “cleanliness” of the 2006 Cleanroom at the time it was certified in 2006 is as follows:

² Liberty arranged for the 2006 Cleanroom to be certified at NECC’s direction. *See* Jul. 10, 2006 e-mail correspondence, a true and correct copy of which is attached hereto as **Exhibit 5**. Liberty was concerned the certification testing may have been premature because, among other reasons, the HVAC system had not yet been balanced, and the room and doorways thereto were not yet completely sealed. *See id.* NECC instructed Liberty to proceed regardless and in fact, the 2006 Cleanroom surpassed expectations and was certified by the third-party company that performs such services. *See e.g.* Exhibit 4 and n.1.

July 12, 2006 Cleanroom Certification Report by ENV Services

Room Description	ISO Class	Max Particle Count Per Cubic Foot	Actual Particle Count Ave Per Cubic Foot	Factor of Cleanliness Level <u>Exceeding</u> Design Requirements
Freight Ante Room	8	100,000	111.25	89.9
Personnel Ante Room	7	10,000	27.75	36.03
Material Prep Room	7	10,000	28.47	28.47
Main Cleanroom	6	1,000	55.44	18.03

13. I have no personal knowledge regarding in which of the rooms the contaminated methylprednisolone acetate (“MPA”) was compounded by NECC. I did observe that the 2005 Cleanroom built by Liberty was not within NECC’s current tenant space and access was denied when I inspected the Facility on July 9, 2014. No person has ever indicated to me in any communication that MPA was compounded in the 2005 Cleanroom. No one has ever indicated to me in any communication that MPA was compounded in the 2008 Cleanroom.

14. During the inspection on July 9, 2014, I observed a one kilogram container of MPA on a counter in the main room of the 2006 Cleanroom. *See e.g.* Figure 17, p.18. I observed MPA nowhere else in the NECC Facility during that visit. This would suggest that the MPA was produced in the 2006 cleanroom. However, Liberty has no direct knowledge of compound(s) manufactured by NECC within the three cleanrooms.

15. Once Liberty completed work on the 2005, 2006 and 2008 Cleanrooms, I did not return to the NECC Facility and perform any additional work. The last construction work done by Liberty at NECC was in connection with the construction of the 2008 Cleanroom for

Ameridose, which was completed in April, 2008. Liberty was not obligated to, was not requested to, and did not perform any modifications to any of the Cleanrooms after 2008.

16. After certification by the third-party contractor, ENV Services, Liberty had no additional contractual obligations to NECC. Liberty had no contractual obligation to and did not determine or monitor whether NECC performed any cleanroom maintenance, cleaning, or contamination control.

17. Liberty did not contract with NECC to provide any maintenance, cleaning, or contamination control services to NECC, or to provide any kind of maintenance services to any part of the Facility. Generally, a customer such as NECC that purchases a cleanroom develops its own standard operating procedures for cleanroom maintenance, cleaning, and contamination control. Liberty did not contract with NECC to monitor whether NECC complied with its own policies regarding such practices.

18. During the course of construction of the 2006 thru the 2008 Cleanrooms, I observed contractors retained by NECC repairing the roof over the cleanrooms constructed by Liberty. I also observed multiple contractors (*i.e.* HVAC, plumbing, electrical, fire suppression, flooring, painters, sheetrock) at the Facility, but never saw anything that would have caused or brought suspicion of causing detrimental harm to any of the three (3) Liberty built Cleanrooms.

19. At no time after the roof work was completed did I observe any leaks or any evidence of leaks. However, during the July 9, 2014 site visit, obvious roof repairs were seen over and above the 2006 and 2008 cleanrooms. *See* Figure 18, p. 18. Holes in the exterior ceiling permitted daylight to shine into the Facility. *See e.g.* Figure 16, p. 18.

20. I observed no conditions that caused me any concern regarding the location of the Cleanrooms while they were under construction in 2005, 2006, or 2008. Sections of floor in the

main room of the 2006 Cleanroom had been redone by NECC and the drywall in areas surrounding the Cleanrooms was new.

21. When I returned to the Facility on July 9, 2014, I observed that solar panels had been installed on the entire south face of the peaked roof on the south side of the NECC Facility. *See* Figure 1, p. 16. Those panels are not over the 2006 or 2008 Cleanrooms. In fact, the solar panels are over a mezzanine area which is separated in the interior by a wall from both the 2006 and 2008 Cleanrooms. No solar panels were in place at the time the 2008 Cleanroom was completed in mid-2008.

22. Based upon the inspection that occurred on July 9, 2014, I observed the following conditions that differed from the condition of the 2006 Cleanroom and the 2008 Cleanroom when I last saw them after their acceptance by NECC:

- There are low wall air return grilles in the walls of both of the cleanrooms. Of these, some were so blocked that they were almost impossible to see, many were totally blocked and all were, at least, partially blocked. *See e.g.* Figure 8, p.17;
- All but two (2) of the door sweeps that were installed by Liberty had been removed as evidenced by the visible holes exposed in all doors where they had been attached. *See e.g.* Figure 14, p. 18. There were gaps of 5/8" to 3/4" between the floor and the bottoms of the doors;
- Five of the six door sweeps were removed on the cart Pass-Thru units. There were gaps of 5/8" to 3/4" between the floor and the bottoms of the doors;
- All plumbing pipe installations made by NECC and/or Ameridose or its contractors that penetrated the walls were not sealed and had no escutcheon plates. *See e.g.* Figure 9, p. 17;

- All of the rooms have cameras, installed by NECC and/or Ameridose or its contractors, mounted on the walls, near the ceiling, with exposed wiring penetrating ceiling tiles without any visible caulking on the cleanroom side, giving the opportunity for foreign matter and contaminants to travel into the cleanrooms;
- Some ceiling tiles showed water damage and some ceiling tiles were missing. *See e.g.* Figure 6, p. 16 and Figure 12, p. 17;
- Exposed ductwork had visible water damage to the fiberglass insulation;
- Several areas showed evidence of water stains on the floor;
- There appeared a general disregard of any cleanroom maintenance protocol:
 - a. Insect carcasses and a small dead bird were present in a cleanroom;
 - b. Filthy unchanged “sticky mats” in several areas of the rooms. *See e.g.* Figures 2 and 3, p.16;
 - c. Unsanitary autoclave. *See* Figure 11, p. 17;
 - d. Holes in the main roof that allowed light to show through. *See e.g.* Figure 16, p. 18;
 - e. Full and overflowing garbage receptacles in and around the cleanroom as well as several of the production units. *See e.g.* Figure 7, p.17 and Figure 15, p.18;
 - f. Rust on several doors, walls, processing equipment. *See e.g.* Figure 5, p.16;

- The Stanley sliding door leading into the Preparation Room for the 2006 Cleanroom was not working. It had damaged and missing gaskets. *See e.g.* Figure 10, p. 17;
- The Cozzuli filling machine, presumably used to fill vials with compounded preparations, was located in the ISO 7 Preparation Room, and less than ten feet from the inoperative Stanley sliding door, which would have allowed for contamination to migrate into the Preparation Room. It is my understanding that filling machines are normally operated in a room with a lower ISO class, *i.e.* a cleaner environment. In addition, the filling machine was located directly below damaged ceiling tiles;
- There were damaged gaskets on all Liberty built and installed Pass-Thru units that were installed in 2006 and 2008. The only undamaged gasket was on a Pass-Thru unit that was labeled “Do Not Use;”

23. The conditions identified in paragraph 22 above adversely affect the operations of the 2006 Cleanroom in the following ways:

- a. The purpose of return grilles is to allow for the air to pass through the grilles to the HVAC system and then to the HEPA filters. With the grilles blocked, the passage of air is prevented, allowing potential contaminants to accumulate on the items placed in front of the grilles;
- b. Removal of the door sweeps makes it extremely difficult to accurately control room pressures and allows for contaminants to enter the room. This condition is even more likely when the HVAC is shut down;
- c. Same potential as (b) above for the cart Pass-Thrus;

- d. Not properly sealing penetrations into the room, such as plumbing, cameras, electrical, *etc.*, results in an inability to maintain room pressures;
- e. If water is allowed to penetrate into the room from any source, the risk of growing mold or bacteria is greatly increased. Water penetration was obvious in several areas of the cleanrooms; and
- f. The filth and squalor prevalent within all the rooms demonstrated a complete disregard, or lack of understanding, as to how a cleanroom should be maintained.

24. However, when I visited the NECC Facility on July 9, 2014, I also observed certification stickers on the hoods in the main room of the 2006 Cleanroom indicating that the hoods were tested and accepted. The certifications on the hoods that I observed in the main room of the 2006 Cleanroom stated the certifications were performed by Scientific Air Analysis, Inc. (“SAA”) and the hoods were certified through December 31, 2012 as indicated on the stickers.

25. Liberty, throughout my tenure as an employee, has been in business as a manufacturer and distributor of cleanrooms and contamination control supplies and accessories. As part of its business, Liberty has never manufactured, compounded, bought, sold, distributed or otherwise handled drugs or any pharmaceutical products for sale to wholesalers, retailers, physicians, hospitals, medical facilities or any other persons. Liberty holds no licenses, registrations or certifications of any kind with the Commonwealth of Massachusetts Board of Pharmacy, with the Federal Drug Administration or any other agency, department or governmental entity regulating the manufacture, sale or distribution of drugs or pharmaceutical products of any kind.

26. More specifically, Liberty has never dealt with MPA in any respect nor did Liberty have any knowledge as to what products were being manufactured at NECC or Ameridose. Liberty also had no knowledge of NECC's compounding practices. Liberty did not manufacture, buy, sell, distribute or deliver MPA to any person asserting claims in the Multi-District Litigation, to any person filing a Proof of Claim in the NECC Chapter 11 proceedings or to any other person at any time.

27. Other than the contracts between NECC and/or Ameridose and Liberty and the performance of work thereunder, Liberty has had no other contracts with NECC or Ameridose to perform work and performed no other work at NECC's Facility.

28. The construction of the Cleanrooms involved generally the following steps:

- a. NECC and/or Ameridose told Liberty what size the cleanrooms were to be, what ISO cleanliness level to design for all the rooms, where they wanted them installed and what the layout of the cleanroom based on their projected layout was to be (dimensions: L x W x H);
- b. NECC and/or Ameridose's flooring contractor performed prepping, finished, primed and base coat the floor;
- c. Liberty installed the structural support system for a walkable ceiling;
- d. NECC and/or Ameridose's HVAC contractor installed all supplied and return air ductwork;
- e. NECC and/or Ameridose's electrical contractor installed preliminary and mechanical wiring, as required;
- f. Liberty installed the prefabricated exterior and interior walls, including door frames;

- g. Liberty installed the walkable ceiling grid system, put in motorized HEPA filters and sealed troffer lights;
- h. NECC and/or Ameridose had the electrician wire wall outlets, HEPA filters, sealed troffer lights and wall switches;
- i. NECC and/or Ameridose had the HVAC contractor make all supply connections to HEPA filters and return air plenums;
- j. Liberty installed all doors and wall mounted Pass-Thrus;
- k. Liberty installed the ceiling tiles and hold down clips;
- l. NECC and/or Ameridose's HVAC air balancer turned the system on and balanced the distribution of air and set room pressures;
- m. Prior to certification, Liberty performed a "superclean" of the entire cleanroom which consisted of wiping down of all ceiling, walls and floors with Liberty's cleaning solution "CRF 440" and its roll mops;
- n. Liberty subcontracted with a third-party certification company that performed the contracted testing; and
- o. If the cleanroom certification test was successful, the cleanroom was handed over to NECC and/or Ameridose as a fully functioning and ready to use cleanroom.

29. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

30. [REDACTED]

[REDACTED]

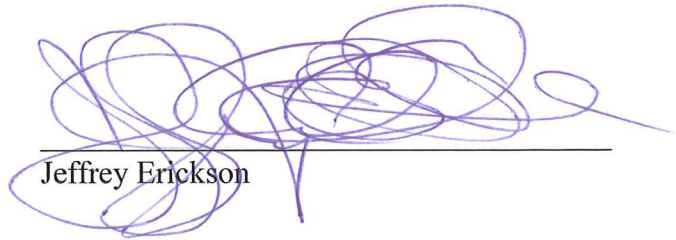
[REDACTED] I understand

that *e. rostratum* is the fungus that allegedly caused the injuries for which claims are made in the MDL proceedings. [REDACTED]

[REDACTED] The dirty side of a HEPA filter is the side away from the interior of a cleanroom. [REDACTED]

[REDACTED] If it had, a third party testing service would have found a defect in the HEPA filter, in which case repairs should have been made and/or a replacement of the HEPA filter would have been warranted. I am aware of no other evidence of contamination of any Cleanroom or any part of any Cleanroom with *e. rostratum*.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY THIS 08 DAY
OF SEPTEMBER, 2014.




Jeffrey Erickson

, ss.

September 08, 2014

On this 08 day of September, 2014, before me, the undersigned notary public, personally appeared Jeffrey Erickson, proved to me through satisfactory evidence of identification, which was license, to be the person whose name is signed on the preceding document who swore or affirmed to me that the contents of the document are truthful and accurate to the best of his/her knowledge and belief.



Notary Public
My Commission Expires: 01/31/2015

PHOTOGRAPHS FROM JULY 9, 2014 SITE INSPECTION



Figure 1 - INSTALLATION OF SOLAR PANELS



Figure 2 - FILTHY STICKY MATS

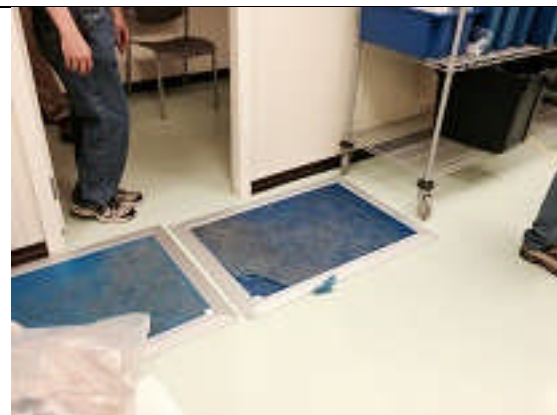


Figure 3 - FILTHY STICKY MATS



Figure 4 - CEILING PENETRATIONS



Figure 5 - RUST ON PROCESSING EQUIPMENT



Figure 6 - MISSING CEILING TILE



Figure 7 - FULL GARBAGE BAG AT PROCESSING EQUIPMENT



Figure 8 - EXAMPLE OF BLOCKED RETURN GRILLES



Figure 9 - IMPROPER PIPING, RUST



Figure 10 - INOPERABLE STANLEY DOOR, DAMAGED GASKETING



Figure 11 - FILTHY AUTOCLAVE

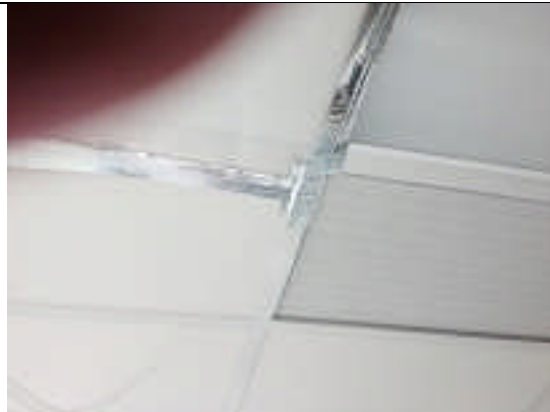


Figure 12 - CEILING TILE



Figure 13 - IMPROPER CEILING PENETRATIONS



Figure 14 - MISSING DOOR SWEEPS

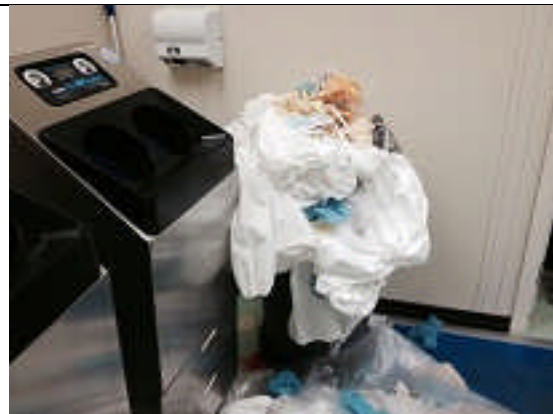


Figure 15 - OVERFLOWING GARBAGE IN THE PROCESSING AREA



Figure 16 - HOLE IN EXTERIOR ROOF WHERE DAYLIGHT SHOWS THROUGH



Figure 17 - CONTAINER OF MPA FOUND IN THE 2006 CLEANROOM



Figure 18 - EVIDENCE OF EXTERIOR ROOF REPAIRS OVER THE CLEANROOM